

## REMARKS

Claims 1-33 are pending in this application. By this Amendment, claim 25 has been amended. The amendments to claim 25 are supported in the specification by at least paragraphs [0022] and [0038]. The amendments place the application in condition for allowance and/or better form for appeal. Accordingly, it is respectfully requested that these amendments be entered.

Claims 1-17 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 1-17 of co-pending application No. 10/726,464. The provisional rejection is respectfully traversed.

Applicant notes that the ground of rejection is non-statutory double patenting which is a new ground of rejection that was not asserted in the prior Office Action (which asserted only statutory obviousness under 35 U.S.C. §101). MPEP §706.07(a) states that "second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period" (emphasis added). Claims 1-17 were not amended in Applicant's April 17, 2006 Amendment and an IDS has not been submitted since the last Office Action. The new ground of rejection was thus not necessitated by an amendment or by information submitted in an IDS. It is thus improper for the new ground of rejection to be asserted in a final rejection, and unfair to deny Applicant the opportunity to respond to the Office Action as set forth in the MPEP. Accordingly, the finality of the rejection should be withdrawn and, if the new ground of rejection is still deemed appropriate, it should be presented in a new non-final office action.

Applicant traverses the provisional non-statutory obviousness-type double patenting rejection of instant claims 1-17 over claims 1-17 of co-pending application No. 10/726,464 (the "464 application"). The Office Action at page 2 asserts only that instant claims 1-17 are not patentably distinct from claims 1-17 of the 464 application because "the longitudinal length and the interior surface area are measurements of the same area of the balloon." Assuming, *arguendo*, that the rejection is based on a comparison of the scope of instant claims 1-17 to the scope of claims 1-17 of the 464 application, Applicant respectfully traverses the rejection because the scope of the claims, by itself, cannot support a double patenting rejection. *See*

MPEP §804(II). Applicant also traverses the rejection because the Office Action fails to establish a *prima facie* case of obviousness.

As noted in the MPEP, "domination" and "double patenting" are two separate issues. *See* MPEP §804(II). Domination refers to when one application has a "broad" or "generic" claim, which reads on an invention defined by a narrower or more specific claim in another application, such that the former application dominates the latter. *See id.* And as further noted in the MPEP, domination (*i.e.*, broad claims in the absence of statutory or non-statutory grounds) by itself cannot support a double patenting rejection. *See id.* Therefore, the burden remains on the Office to establish a *prima facie* case of obviousness as to why one of ordinary skill in the art would conclude that the inventions recited in instant claims 1-17 are an obvious variant of the invention recited in claims 1-17 of the 464 application. That is, there must be a suggestion or teaching in the 464 application that would motivate one of ordinary skill in the art to modify the invention recited in claims 1-17 of the 464 application in order to reach the invention recited in instant claims 1-17.

Applicant respectfully submits that there is no suggestion or motivation provided by the Office, and the Office Action thus fails to establish a *prima facie* case of obviousness. Furthermore, it is respectfully submitted that "length" and "area" have fundamentally different meanings and can not reasonably be viewed to be the same thing as asserted in the Office Action. Accordingly, the double patenting rejection should be withdrawn.

Furthermore, claims 1-17 of the above-identified application are patentably distinct from claims 1-17 of the 464 application. Claims 1-17 of the 464 application recite, at least, a balloon with a longitudinal length that remains substantially unchanged whereas instant claims 1-17 recite a surface area of a balloon that remains substantially unchanged. Accordingly, for the forgoing reasons, it is respectfully requested that the non-statutory double patenting rejection be withdrawn.

Claims 1-12 and 15-17 stand rejected under 35 U.S.C. §102(b) over Hamlin (U.S. Pat. No. 5,270,086); claims 18-33 stand rejected under 35 U.S.C. §102(b) over Euteneuer (U.S. Pat. No. 4,952,357); and claims 13 and 14 stand rejected under 35 U.S.C. §103(a) over Hamlin in view of Trotta (U.S. Pat. No. 5,290,306). The rejections are respectfully traversed.

Independent claims 1 and 18 stand rejected under 35 U.S.C. §102(b), which is interpreted by the Office to require the following:

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. ... The identical invention must be shown in as complete detail as is contained in the ... claim.

MPEP §2131 (emphasis added). The MPEP also states that:

The distinction between rejections based on 35 U.S.C. 102 and those based on 35 U.S.C. 103 should be kept in mind. Under the former, the claim is anticipated by the reference. No question of obviousness is present. In other words, for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present.

MPEP §706.02(IV). The Office Action fails to identify where fibers are directly shown or described in Hamlin or Euteneuer and, at page 6, the Office Action acknowledges that "fiber" is not expressly disclosed in Hamlin. The Office Action also refers to information that is not described in the applied references where it asserts that the deficiencies of Hamlin are remedied because "it is well known in the material science art that these materials are different types of fibers." However, the Office Action's reference at page 6 to what is "well known" in the art is irrelevant to a rejection under 35 U.S.C. §102 because the procedure for relying on common knowledge in a rejection is limited to rejections under 35 U.S.C. §103(a). See MPEP §2144 and §2144.03.

Since Hamlin and Euteneuer are silent regarding fibers, and because the rejections are based on 35 U.S.C. §102, the Office Action appears to assert that Hamlin and Euteneuer each inherently describe fibers. MPEP §2112(IV) states that:

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

The Office Action fails to conform with MPEP §2112(IV) because it does not make clear that any of the materials described in Hamlin would necessarily contain fibers. Moreover, Hamlin

clearly describes that the materials forming the layers of parison 40 are molten when formed, which would suggest that Hamlin's materials do not contain solids such as fibers. See Hamlin at col. 4, lines, 46-49. The Office Action also fails to conform with MPEP §2112(IV) and §2131 because it does not set forth where Euteneuer shows or describes fibers, either expressly or inherently.

Hamlin also fails to show or describe a non-compliant medical balloon having a first fiber layer and a second fiber layer, as recited in claim 1. For the reasons of record and asserted above, Hamlin fails to show or describe fiber layers. Hamlin is limited to certain polymers that, when molten, form a two-layer parison 40 (see Hamlin at col. 4, lines, 46-49) and, at least because of this melting of Hamlin's polymers, Hamlin can not by fairly read to describe materials containing solid fibers in a fiber layer.

Furthermore, Hamlin fails to show or describe fibers of a first fiber layer and fibers of a second fiber layer forming an angle, as recited in claim 1. The Office Action at page 2 asserts that Fig. 5 of Hamlin show "layers [that] are angled," but the purported angle of Hamlin's layers (inner layer 48 and PET layer 56) is not relevant to claim 1 because the claim recites "... fibers ... forming an angle ..." Fig. 5 of Hamlin shows a cross section of parison 40 and it does not show or describe the orientation of the materials of parison 40.

With regard to Euteneuer, Euteneuer fails to show or describe a non-compliant medical balloon having a first fiber and a second fiber, as recited in claim 18. Euteneuer does not refer to "fibers" and can not be read to expressly show or describe fibers. To the extent the Office Action asserts that Euteneuer inherently shows or describes fibers, such an assertion fails to conform with MPEP §2112(IV) because the Office Action does not make clear that any of the materials described in Euteneuer would necessarily contain fibers.

Moreover, as Hamlin fails to disclose fibers (according to page 6 of the Office Action), Fig. 5 of Hamlin can not be interpreted to show fibers or an angle between fibers. Applicant notes that the Office Action cites to the figures of Hamlin and Euteneuer to support its assertion that fibers or fiber layers are shown in these references. As Fig. 5 of Hamlin and Fig. 2B of Euteneuer fail to show or describe the materials of the Hamlin or Euteneuer devices, it appears that the Office Action is interpreting the cross-hatching in those drawings to represent an internal arrangement of fibers in layers 48 and 56 of Hamlin and substrate 30 and film 40 of Euteneuer. Applicant respectfully brings to the Examiner's attention that such an interpretation (if in fact

relied upon) is contrary to 37 C.F.R. §1.84(h)(3) and MPEP §608.02(IX). Specifically, the spacing and angle of cross hatching in Hamlin and Euteneuer is due to the requirements of 37 C.F.R. §1.84(h)(3), which mandates the use of regularly spaced parallel oblique strokes. Also, cross hatching can, at most, identify only a type of material under MPEP §608.02(IX), and thus does not identify a particular arrangement or internal structure of a material.

Trotta fails to remedy the above-described deficiencies of Hamlin and Euteneuer. Trotta does not show or describe fibers or fiber layers.

For the foregoing reasons, the applied references fail to show, describe, teach, or suggest the claimed invention as a whole as recited in the independent claims or the dependent claims thereof. It is respectfully requested that the rejections be withdrawn.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this Application and the prompt allowance of at least claims 1-33.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-3840. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).**

Respectfully submitted,



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